UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/038,894	03/11/1998	ROLAND STOUGHTON	24730-2202	8909

24961 7590 06/18/2003

HELLER EHRMAN WHITE & MCAULIFFE LLP
4350 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122-1246

EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/18/2003 40

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/038,894	STOUGHTON ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18,32-36,38,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18,32-36,38,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 38 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

The election of species of record is maintained for the reasons of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 32-36, 38, 41, 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has argued that this paragraph has been met but it has not been shown on the record that the disease is totally gone. To prevent a disease it must be totally eliminated. Without evidence that the disease is totally prevented meaning that there is absolutely no disease present, the claims are not enabled.

Claims 10-18, 32-36, 38, 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hemorrhagic shock by assessing for free radical production using phenol red and then if levels are elevated using futhan, does not reasonably provide enablement for any and all activation lowering therapies and any and all diseases or conditions and any and all methods of assessing cellular activation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for treating hemorrhagic shock by assessing for free radical production using phenol red and then if levels are elevated, using futhan, but is not enabled for any and all activation lowering therapies and any and all diseases or conditions and any and all methods of assessing cellular activation .

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all activation lowering therapies and any and all diseases or conditions and any and all methods of assessing cellular activation to see if they could perform the claimed processes. With knowing only one activation lowering therapy, one condition to treat it with and only one type of assay in which to determine if it is necessary, one of ordinary skill in the art would not know what other conditions could be treated, what other therapies could be used or what other assays could be used to determine if such a method would work. Simply because such a method works with this combination does not mean that it will work for any and all

combinations. The area of biotechnology is highly unpredictable since the human body in and of itself is very unpredictable.

Applicant has only shown treating hemorrhagic shock by assessing for free radical production using phenol red and then if levels are elevated, using futhan. With only knowing this one combination of steps to yield the claimed method, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given this one combination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-18, 32-36, 38, 41, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 32, how can the method perform a prophylaxis, diagnosis, and treatment all at the same time ? Applicant argues that the method is a way of diagnosis and that it does not treat a condition or disease. Which is it ? Applicant is trying to have it both ways. They argue that the references only teach treating the condition or disease and that the claims are drawn to a diagnosis but the claims do not reflect this argument.

In claim 32, it is not clear what "cell activation" is. Activation of what in the cell ? What activity is being activated, enzyme activity ?

Further, it is not clear what the phrase, "if elevated" is relative to. How does one know if the elevation level has been met ? What level has to be reached to qualify as "elevated" ?

Also, it is not clear what is meant by "administering activation lowering therapy". Is this a method or a compound which is being administered ?

Further, it is not clear what is meant by "preventing a disease or disorder" ? For the disease to be prevented the disease would have to be totally eliminated. From reading the specification this is not what has happened. Thus, it is unclear how the claim is to be interpreted since prevention is not taught and one of ordinary skill in the art would assume that the disease is totally absent when it is prevented.

Claim Rejections - 35 USC § 103

Claims 10-18, 32-36, 38, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada 1 (of record), Okada 2 (of record), Yanamoto et al., or Yonekura et al. in view of Gibboni et al., Pick et al., Babcock et al., and Brunck et al.

Applicant has argued that the references merely administer the futhan and that they do not first measure cell activation before administering the futhan.

This is not well taken since as explained on the record, a doctor would want to check such levels before administering the futhan since otherwise the futhan would not be needed. This is a 35 USC 103 rejection because of this step otherwise it would have been a 35 USC 102 rejection if the futhan were simply administered. Why would

someone administer a medication if the person did not show any symptoms of needing the medication ? The first step of claim 32 is to assess the cell activation which will tell the doctor if the patient needs the medication. This is a normal thing for a doctor to do.

A doctor routinely checks his/her patients for blood pressure, temperature, etc. Why does applicant think that a doctor would not check his patient for any type of disorder or disease ? Claim 32 is so broad in that it reads on any type of "cell activation" of any condition or disease. There is nothing specific about claim 32.

If one were to follow applicant's logic, then a doctor would only check his patient's temperature if the patient showed any signs already of having temperature. Since this is absolutely not true in the practice of medicine, then one of ordinary skill in the art also would check for "cell activation" to see if any levels of the patient had been elevated which is relative in and of itself.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM
June 13, 2003